

Please amend the above-identified application as follows:

**Amendments to the claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended): Method for selecting a particular population of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value equal or higher than 5.5, which value is calculated as the ratio between respectively the percentage of women having no pathologies, comprising the following steps in order:
  - a) ~~determination~~ determining ~~of~~ the levels of sialidase ~~by means of the procedure described in Cauci et al. Am J Obstet Gynecol 1998; 178; 511-5 and/or prolidase activity by means of the procedure described in Cauci et al. J Infect Dis 1998; 178; 1698-706~~ in samples of body ~~—~~ cervo-vaginal fluid;
  - b) ~~determination~~ determining ~~of~~ the pH value of said ~~body fluid~~ samples; and
  - c) selecting the samples having a sialidase value equal or above 5.0 nmol of methoxyphenol and/or a prolidase level equal or above 1500 mOD for prolidase and a pH  $\geq 5.0$ .
2. (original): Method as set forth in claim 1, in which the pH is  $\geq 5.0$  and  $\leq 7.0$ , preferably  $\geq 5.0$  and  $\leq 6.0$ , more preferably  $\geq 5.0$  and  $\leq 5.5$ .
3. (original): Method as set forth in claim 1, in which after the a) phase a score of said levels of sialidase and/or prolidase activity is determined.
4. (canceled)

5. (currently amended): Method as set forth in claim 1, in which the obstetric or gynecologic pathologies comprise: low birth weight (LBW), very low birth weight (VLBW) preterm delivery (PTD), early preterm delivery (EPTD), premature rupture of membranes, preterm premature rupture of membranes, intraamniotic infections, spontaneous abortion, endometritis, obstetric surgery infections, post-partum or post-gynecologic surgery infections, pelvic surgery infections, upper genital tract infections which cause infertility, pelvic inflammatory disease (PID), annexitis, cervicitis, sexually transmitted diseases and infections, ~~malignancies of the urogenital tract~~ or cervical cancer.
6. (original): Method as set forth in claim 1, in which said population of women has the risk of said pathologies at a period of gestation less than 37 weeks, preferably less than 35 weeks, more preferably less than 32 weeks.
7. (currently amended): Method as set forth in claim 1, in which said method is carried out in samples of ~~body~~ cervo-vaginal fluid of pregnant women.
8. (currently amended): Method as set forth in claim 7, in which said method is carried out in samples of ~~body~~ cervo-vaginal fluid of women in the first or second trimester of gestation.
9. (currently amended): Method as set forth in claim 7, in which said method is carried out in samples of ~~body~~ cervo-vaginal fluid of women from the sixth to the twenty-fourth full week of gestation.

10. (currently amended): Method as set forth in claim 1, in which said method is carried out in samples of ~~body~~ cervo-vaginal fluid of non-pregnant women.

11. (original): Method as set forth in claim 1, in which said OR value is calculated and corrected by a standard factor by the SPSS computer statistic program.

12. (currently amended): Method for selecting a particular population of women having a risk of developing, VLBW, delivery at < 37 weeks' gestation, < 35 weeks' gestation or < 32 weeks' gestation, comprising the following steps in order:

a) ~~determination of~~ determining the levels of sialidase ~~by means of the procedure described in Cauci et al. Am J Obstet Gynecol 1998; 178; 511-5 and/or prolidase activity by means of the procedure described in Cauci et al. J Infect Dis 1998; 178; 1698-706 in a sample~~ samples of body cervo-vaginal fluid;

b) ~~determination of~~ determining the pH value of said ~~body fluid sample~~ samples; and

c) selecting the samples having a pH  $\geq 5.0$  and a sialidase value above 0.19 nmol of methoxyphenol and/or a prolidase value above 22 mOD.

13. (original): Method according to claim 12, wherein the step c) comprises selecting the samples having a pH  $\geq 5.0$ , sialidase level of over 2.50 nmol of methoxyphenol or prolidase level of over 1000 mOD.

14. (original): Method according to claim 12, wherein the step c) comprises selecting the samples having a pH  $\geq 5.0$ , a sialidase value above 0.19 nmol or 0.38 nmol or 2.5 nmol of methoxyphenol when it is selected a prolidase value of over 1000 mOD.

15. (original): Method according to claim 12, wherein the step c) comprises selecting the samples having a  $\text{pH} \geq 5.0$ , a sialidase value of 0.38 nmol of methoxyphenol and a prolidase value of over 22 mOD or over 44 mOD or over 1000 mOD or over 1500 mOD or over 2000 mOD.

16. (original): Method according to claim 12, wherein said risk is indicated as OR value equal or higher than 5.5, which value is calculated preferably by the SPSS computer statistic program.

17. (withdrawn): Kit for the determination of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value higher than 5.5, calculated preferably by the SPSS computer statistic program, comprising a sialidase and/or prolidase activity assay in solution that includes a colorless substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of methoxyphenol and/or the level of prolidase equal or above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a  $\text{pH} \geq 5.0$  and an illustrative leaflet containing the instructions for the proper use of the kit.

18. (withdrawn): Kit according to claim 17, wherein said kit is used with a sample of body fluid of women.

19. (withdrawn): Kit according to claim 17, wherein said body fluid is a vaginal fluid.
20. (withdrawn): Kit according to claim 17, wherein said pH indicator comprises a revealing paper with a turning interval in the range between 5.0 and 7.0, preferably between 5.0 and 6.0, more preferably between 5.0 and 5.5.
21. (withdrawn): Kit according to claim 17, wherein said reference scale for the sialidase and/or prolidase activity reports standard values associated with enzyme detecting colors.
22. (withdrawn): Kit according to claim 21, wherein said reference scale for pH value associates said turning interval with a particular color intensity of the same color.
23. (withdrawn): Kit according to claim 17, wherein said illustrative leaflet correlates the enzymatic activity with the pH value in order to evaluate the risk of pathologies as: absent or low (-), medium (+), high (++), very high (+++).
24. (withdrawn): Kit according to claim 16, including a test on solid support, preferably on reactive strip or platform test, for the determination of the sialidase and/or prolidase activity.

25. (withdrawn): Kit according to claim 17, comprising as chromogenic or fluorogenic substrate for the determination of sialidase activity a reagent chosen in the group comprising: 2-(3'-methoxyphenyl)-N-acetyl-D-neuraminic acid, 2-O-(o-nitrophenyl)-alfa-D-N-acetyl neuraminic acid, 2'-(4-methylumbelliferyl)-alfa-D-N-acetyl neuraminic acid sodium salt, 5-bromo-4-chloro-3-indolyl-alfa-D-N-acetyl neuraminic acid.

26. (withdrawn): Kit according to claim 25, comprising as chromogenic or fluorogenic substrate for the determination of prolidase activity a reagent chosen in the group comprising: L-proline-para-nitroanilide, L-proline-beta-naphthylamide, N-benzyloxycarbonyl-L-prolyl-beta-naphthylamide, N-benzyloxycarbonyl-L-proline-para-nitrophenyl ester, hydroxy-L-prolyl-beta-naphthylamide, L-proline-7-amido-4-methylcoumarin, L-proline-4-methoxy-beta-naphthylamide.

27. (withdrawn): Kit for the determination of women having a risk of developing LBW, VLBW, PTD, delivery at < 37 weeks' gestation, < 35 weeks' gestation or < 32 weeks' gestation, comprising a sialidase and/or prolidase activity assay in solution that includes a colorless substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of methoxyphenol and/or the level of prolidase equal or above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a pH  $\geq 5.0$  and an illustrative leaflet containing the instructions for the proper use of the kit.

28. (new): Method for selecting a particular population of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value equal or higher than 5.5, which value is calculated as the ratio between respectively the percentage of women having no pathologies, comprising the following steps in order:

- a) evaluation of the levels of sialidase enzyme activity in said sample of cervo-vaginal fluid;
- b) provision of a value indicative of the risk;
- c) comparing said levels of sialidase enzyme activity obtained from the step a) with said value indicative of the risk provided in step b);
- d) calculation of risk factor, wherein said value indicative of the risk is obtainable by a method comprising the steps of:
  - i) providing a group of women whose body fluid samples have sialidase enzyme activity;
  - ii) evaluating the levels of sialidase enzyme activity in such a group;
  - iii) calculating the percentage of women of said group who had said pathologies and who had no pathologies; and
  - iv) calculating a value and its correction with a standard factor on the basis of the percentage obtained in step iii) in order to evaluate the value indicative of the risk.